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Mr Jackie J Schwartz
1350 BROADWAY
SUITE 1507
New York, NY 10018-7702

EXAMINER

PATTEN, PATRICIA A

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/18/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,923

Applicant(s)

Kennedy, P.

Examiner

Patricia Patten

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 6, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above, claim(s) 1-3 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-19 and 21-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claims 1-32 are pending in the application.

Election/Restriction

Applicant's election of Group I, claims 4-19 and 21-32 in Paper No. 3 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 1-3 and 20 have been withdrawn from further consideration on the merits as being drawn to a non-elected invention.

- Claims 4-19 and 21-32 have been presented for examination on the merits.

Trademarks

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The use of the trademark has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claims 4, 11, 19 and 31 are objected to for the following informalities:

Claim 4 does not have a comma in between the words 'gels' and 'lotions' in line 8.

Claims 11, 19 and 31 all recite 'PCMX.' It is suggested that 'PCMX' be spelled out in its entirety at the first instance of its appearance in order to avoid confusion with any other products which may share this abbreviation.

Claim 13 recites 'The pharmaceutical composition' however, appears to be an independent claim. It is suggested that the preamble of the claim be changed to 'A pharmaceutical composition..' in order to overcome this objection. The claim was examined on the merits as if it was an dependant claim.

Claim 32 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

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required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, the claim states wherein 'said abrasive ingredient and anti-itch enzyme are applied as a celation in an aqueous pharmaceutical carrier.' This does not limit the composition as claimed in claim 22 *per se*. Rather, it adds functional limitations which do not further limit the composition. It is suggested that if Applicant intends to limit claim 32 to including an aqueous pharmaceutical carrier, than the claim be amended to read 'The pharmaceutical composition according to claim 22 wherein said composition further includes an aqueous pharmaceutical carrier.' Although this claim does not properly limit claim 22, the claim was examined as if it were drawn to the composition further comprising an aqueous carrier.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 11, 13, 19, 21, 22 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 4 recites an improper Markush group. Namely, claim 4 recites 'an abrasive ingredient' such as glass or ground crab shells as well as 'any sort of brush' or 'abrasive applicators' and 'a carrier.' First, all of the plural constituents found in the Markush group lack antecedent basis in the claim since the claim stated 'ingredient' and 'a carrier' previously. The term 'said active ingredient' also lacks antecedent basis in the claim. The phrase 'any sort of brush' is not understood. Does this mean 'brush' as in a 'hair brush' or does it mean plant material? Further, the members 'brush' and 'applicators' are not properly placed in the Markush group because they would not be considered able to form a 'pharmaceutical composition' *per se*. Rather, it appears that an applicator along with a carrier would be better claimed as a 'kit' since it is not commonly accepted as a 'composition'.

Additionally, proper Markush practice follows the format; '...selected from the group consisting of A, B, C and D.' In the instant case, Applicants have recited 'selected from the group thereof consisting of...'. It is not known what 'thereof' is referring to, and thus it is confusing. Further, 'all at 35-60 mesh' appears to be present in the Markush group. The following is a suggestion for amending the claim in order to overcome this rejection:

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A pharmaceutical composition for topical application to sites of insect bites and stings to relieve itch, pain, and swelling associated therewith, comprising an effective amount of an abrasive ingredient and a carrier;

wherein said abrasive ingredient is selected from the group consisting of walnut shell pumice, plastic material, sand, stone, glass, seed shell, fruit shell, seed, metal, chitosan and crab shell;

wherein said carrier is selected from the group consisting of.....(all singular); and

wherein said abrasive ingredient is ground to 35-60 mesh.

Claim 13 recites 'The pharmaceutical composition' however, does not depend from another claim. Thus, the phrase lacks antecedent basis in the claim.

Claims 11 and 19 and 31 are all improper Markush groups. Claims 11,19 and 31 are drawn to groups of anesthetics, however, all of the constituents are not known anesthetics. For example, calamine, iodine, hydrogen peroxide as well as many other members of the Markush group are not known anesthetics except for benzocaine and lidocaine and perhaps some fruit oils (as far as the Examiner can tell). Because all of the members of the group appear to be pharmaceutically diverse constituents, it is suggested that either the term 'anesthetic' be deleted from the preamble of the claims, or the claims be limited to lidocaine and benzocaine (or other known anesthetics which

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are in the Markush group) absent evidence that all of the other constituents indeed act as anesthetics.

Claim 11 recites 'in the form of a powder.' This phrase appears to lack antecedent basis in claim 4 in that the constituents which make up the carrier are all in liquid form; i.e., mineral oils, sops, gels and lotions. Thus, it is suggested that claim 11 recite a missing step which would cause the composition of claim 11 to be present as a 'powder' without adding new matter.

Claim 21 recites 'the human skin.' This phrase lacks antecedent basis in the claim.

Claim 22 recites 'said active ingredient.' This phrase lacks antecedent basis in the claim.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Claim 22 states wherein the abrasive ingredients are selected from constituents such as stone or glass. These ingredients would not necessarily be 'abrasive' per se without grinding the ingredients. For example, a stone may be round and smooth, and glass may also have rounded edges, thereby not

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constituting an 'abrasive ingredient.' Therefore, the claim also lacks antecedent basis with regard to claim 21. It is recommended that the limitation from 23 into claim 22 in order to overcome this rejection.

Claim 22 is also rejected for the recitation of 'any sort of brush' and 'abrasive applicators' as pointed out *supra*. The claim is also an improper Markush group in that it states 'selected from the group consisting of A, B or C, rather than proper Markush practice which would recite 'selected from the group consisting of A, B and C.'

Claims 11, 19 and 31 contain constituents which are divided, such as aloe/aloe vera. It is not known if this means 'aloe or aloe vera' or 'aloe and aloe vera' (in addition to any other constituents which are separated by '/'). Correction is necessary.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 21-22, 24-26, 28, and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Product Alert (1998) in light of Miner (2002)*. Claims 21-22, 24-26, 28 and 30-32 are drawn to a composition comprising an abrasive ingredient such as shells or stone or glass, wherein the composition comprises a carrier such as emollients or gums for example, wherein the composition contains an enzyme such as papain, wherein the composition is in the form of a lotion, paste, or liquid, wherein the composition additionally includes an anesthetic, or constituents such as methylparaben or iodine for examples, and wherein the abrasive ingredient and said anti-itch enzyme are applied as a solution in an aqueous pharmaceutical carrier.

Product Alert (1998) disclosed a cosmetic sold by Origins Natural Resources (ONR) named 'Never a Dull Moment' (NDM). As evidenced by Miner (2002), the 'Never a Dull Moment product disclosed by Product Alert contains papain, ground mango, apricot and walnut shells, pine, eucalyptus, bitter almond, rose essential oils, edta, polysorbate 80, and methyl, ethyl, propyl and butylparaben as a few examples (see, e.g., top of second page). Pine is a known anesthetic.

The Examiner has given the terms 'liquid' 'paste' and 'lotion' their broadest interpretation within reason, and deemed that NDM could be described as a 'paste' or a 'lotion' and appears to display the properties of a 'liquid' especially lacking credible evidence to the contrary.

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Wherein claims state 'for the topical application...of insect bites and stings to relieve the itch, pain, and swelling associated therewith' is merely an intended use of a known composition:

Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). "When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated" (MPEP 2100 pp. 2113).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-19 and 21-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Product Alert (1998) in light of Miner (2002)* in view of Tseng et al. (US 5,716,634). Claims 4-19, 23 and 27-29 are drawn to a composition comprising an abrasive ingredient such as shells or stone or glass, wherein the composition

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comprises a carrier such as emollients or gums for example, wherein the composition contains an enzyme such as papain, wherein the composition is in the form of a lotion, paste, or liquid, wherein the composition additionally includes an anesthetic, or constituents such as methylparaben or iodine for examples, wherein the abrasive ingredient and said anti-itch enzyme are applied as a solution in an aqueous pharmaceutical carrier and wherein the abrasive ingredient is ground to a mesh size between 35-60 mesh.

Product Alert (1998) disclosed a cosmetic sold by Origins Natural Resources (ONR) named 'Never a Dull Moment' (NDM). The product, as described by Product Alert and Miner (2002), contains papain, ground mango, apricot and walnut shells, pine, eucalyptus, bitter almond, rose essential oils, edta, polysorbate 80, and methyl, ethyl, propyl and butylparaben as a few examples. Pine is a known anesthetic.

Product Alert did not teach wherein the NDM sold by ONR contained shells or seeds ground to 35-60 mesh.

Although the reference did not teach wherein the product contained granules at the recited mesh sizes as Instantly claimed, it was routine in the art to grind shells and seeds to various mesh sizes to incorporate these granules into cosmetic compositions suitable for 'exfoliating' the skin. Tseng et al. for example, disclosed polymers for cosmetic use which were created to pass through mesh sizes anywhere between 40 to

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350 mesh. Thus, it would not have taken a considerable contribution from the ordinary artisan to have ground the shells and/or seeds to 40 - 60 mesh for example, in order to have created a cosmetic composition which contained 'finely ground' (Product Alert) particles for cleansing the skin since particles in this size were routinely added to cosmetics.

ONR sells NDM in a cream/lotion form but did not disclose a 'powder' form of the composition. However, the form of the composition would not have materially changed the overall make-up of the composition as a whole. It was routine in the art to have created varying forms of cosmetic compositions in order to suit the demands and needs of the general public. For example, soaps are commonly sold as bars or liquids due to individual's preferences. However, the 'form' of the soap does not materially change the overall characteristics of the soap itself; cosmetically, it performs the same function whether a 'bar' or a 'liquid.' (Please also see rejection under 35 U.S.C. 112 Second Paragraph *supra* re: the term 'powder').

Because NDM contained methylparaben, claim 11 is obviated by NDM even though methylparaben is not commonly known as an anesthetic.

Although the NDM product did not contain the specific carriers as cited in Claim 13, NDM did contain various suitable cosmetic carriers such as polysorbate 80 and phenoxy ethanol. Claim 13 states 'polysorbate 60.' Substitution for carriers was routine in the art. The addition of polysorbate 60 rather than polysorbate 80 would

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have been a minor adjustment which would not have made any significant difference in the cosmetic properties of the composition. The selection of polysorbate 60 therefore, would have merely been a matter of judicious selection on the part of the ordinary artisan.

* Please note that this reference is cited merely to relay inherent properties of the composition, and that the reference is not being used as a prior art reference *per se*.

Claims 4-19 and 21-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greene (1996) in view of Tseng et al. (US 5,716,634). The nature of claims 4-19 and 21-32 were discussed *supra*. Applicant is claiming a product for alleviating the pain and sting of insect bites via the use of a composition comprising abrasive materials and anesthetics and optionally a digestive enzyme such as papain.

The teachings of Tseng et al. were discussed *supra*.

It was well known in the art that bee stings were commonly treated with meat tenderizer which contained papain (a digestive enzyme) and grains of salt (abrasive). As disclosed by Greene, other common treatments for bee stings included taking oral antihistamines, applying calamine lotion, taking oral pain relievers and applying topical hydrocortisone (antihistamine).

Greene did not specifically teach admixing the claimed ingredients.

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It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each was well known in the art for treating bee stings. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore obvious.

It is not known exactly what the mesh size of the salt present in meat tenderizer is. However, it is deemed that the size of the salt grains in meat tenderizer would probably be in the range of about 40-300 mesh, which, according to Tseng et al. was clearly suitable for cosmetic purposes.

Again, the 'form' of the composition would not have materially changed the composition (*supra*).

The addition of all of the claimed ingredients together in a composition with known carriers/emulsifiers would have been obvious to one of ordinary skill in the art with the cited references before him. Because all of the individual ingredients were known in the art for treating stings, one of ordinary skill in the art would have been motivated to have combined the instant ingredients for mere ease of administration/manufacture.

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Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, consisting of a stylized 'C' and 'R' intertwined, followed by a horizontal line.

CHRISTOPHER R. TATE
PRIMARY EXAMINER